

# PATENT SPECIFICATION

693,224



Date of filing Complete

Specification: July 13, 1951.

No. 10097/50.

Application Date: April 24, 1950.

Complete Specification Published: June 24, 1953.

Index at acceptance:—Class 81(ii), B17e.

## COMPLETE SPECIFICATION.

### Rubber drainage Tubing, Catheters or the like with distensible bags and the manufacture thereof

We, ROBERT HANS MÜLLER, PH.D., a British Subject, and J. G. FRANKLIN & SONS LIMITED, a British Company, both of Birkbeck Works, Colvestone Crescent, 5 London, E.8, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to rubber drainage tubing, catheters, or the like, with distensible bags (hereinafter in this specification and the claims hereof termed 15 bag catheters), and the manufacture thereof, and has for its principal object to provide a distensible bag catheter in which the bag will distend symmetrically or substantially so and the tubing remain straight or 20 substantially so while the bag is distended. The term rubber as used in this specification is to be understood as including both natural and artificial rubber.

Distensible bag catheters generally consist of a principal drainage tube provided 25 with a circumferential bag portion proximal to the drainage eyelets, and having an independent distension duct extending longitudinally along the drainage tube to the bag for inflating this so as to distend 30 the bag when the catheter is in place.

The manufacture of such catheters by a dipping process is well known.

One way consists in depositing rubber 35 from a solution or dispersion on a rod-like former to form the principal drainage tube, attaching a thinner auxiliary tube alongside the main tube and affixing a thin rubber bag or bag-forming portion (hereinafter in this specification and in the 40 claims hereof termed bag) around the tubing in such a way that this bag adheres or connects firmly to the tubing at both its end portions and can be freely inflated

The main and auxiliary or inflation tubes together form what is herein called "the body" of the catheter.

For preference the bag is formed by an annular band or sleeve of thin rubber 50 which initially, at least at its opposed end portions, closely fits the outside of the catheter body, this band or sleeve being internally connected at both its end portions to the body of the catheter by adhesion, so that a medial portion of the band of uniform length can be distended by inflation. One or more external coatings of rubber may be applied over the whole assembly to attach the band more 60 securely to the catheter body, and promote a smooth external finish.

In the manufacture of these bag catheters, one of the difficulties encountered is to produce an article in which the bag 65 will distend symmetrically and in such a way that the main drainage tubing will remain substantially straight and extend substantially centrally of the inflated bag when the article is in use. 70

When the bag is distended to the bulbous or hollow ring-like configuration required in use, the rubber of the bag is necessarily greatly stretched and the considerable forces exerted may tend to pull 75 local inward parts of the connected end portions of the bag away from the body of the catheter so that the circumferential zones of connection between the bag and the catheter body become locally or unevenly reduced around the circumference of the body so that variation is introduced around such circumference in the length of the inflatable portion of the bag. 85

As soon as the length of the inflatable portion of the bag varies around the circumference of the body a couple is produced on inflation with the result that the

corresponding end of the tubing becomes bent.

We have found that the main factor requisite for a symmetrical distension of the 5 bag, and also for preventing the drainage tube from bending, is the provision at the end boundaries of the distensible portion of the bag, and the maintenance under inflating pressure, of sealing contact between 10 the bag and the catheter body around circumferential lines lying in substantially parallel planes exactly or approximately at right angles to the axis of said body.

For the purpose of establishing and 15 maintaining this condition of connection the present invention consists in the application of relatively inextensible binding, e.g., of fabric or a suitable thread such as rayon, cotton or silk around the end portions of the bag.

In one way of carrying out the invention the main and auxiliary tubing and the bag in the form of a band, are produced, e.g., by immersion of suitable formers in liquid 25 rubber composition and then combined in the usual way, opposed end portions of the band being joined at circumferential junction zones to the catheter body by adhesion.

30 After the bag has been thus secured to the body at least one strip of fabric or one or more turns of suitable thread as aforesaid are firmly secured around the end portions of the bag in such a way that the 35 inflatable portion of the bag is bounded at its ends by circumferential lines of contact, maintained by the bindings, such lines being in parallel planes at right angles to the axis of the catheter body. If desired 40 a further coating of rubber may be deposited, e.g., by dipping, over the whole combination.

We prefer to hold the binding in position by adhesion to the material of the bag e.g., 45 by applying the binding while the rubber material of the bag is in a semi-dry condition and to maintain the binding pressure while such material dries. Alternatively, the bindings or the band where the bindings 50 are to be applied may be coated with an adhesive. In this way the use of knots in a thread binding is obviated. In the case of a single turn of thread or a single turn of a fabric strip binding as aforesaid 55 the ends of the binding may abut or overlap.

For the purposes of the present invention the liquid rubber composition from which the component parts of the catheter 60 are formed, may be a solution of rubber in a solvent such as the so-called rubber cement, or a natural or artificial latex.

may contain vulcanising ingredients or may consist of pre-vulcanised dispersions.

In the formation of the catheter body, cohesion of the rubber ordinarily will be sufficient to hold the assembled main and 70 auxiliary tubing in proper relation for subsequent handling, but this adhesion may be augmented if necessary by rubber cement. The assembled tubing may be immersed again in the liquid rubber com- 75 position and an additional coating of rubber produced upon the assembly to build up a deposit of rubber merging with the previous deposits to provide an overall coating about 0.01 to 0.10 in thickness 80 and to promote a smooth exterior surface to the assembly.

Instead of forming the bag separately and then securing it to the catheter body, the catheter body may be used as a former 85 for production of the bag in situ by immersion, as will be later described.

Strips of fabric or the like may be used instead of thread-like bindings. In this case the strips must be applied to that the 90 inner edges of the opposed strips maintain the desired circumferential lines of sealing contact at the end boundaries of the inflatable portion of the bag.

In order that the present invention may 95 be the more readily understood, reference is hereinafter made to the catheter illustrated by way of example in the accompanying drawings, in the production of which use has been made of the present 100 invention.

In the drawings:—

Fig. 1 is an elevational view of the bag catheter;

Figs. 2 and 3 are undistended and distended longitudinal sections thereof.

Fig. 4 is an enlarged longitudinal section; and Fig. 5 is a transverse section on the line 5-5 of Fig. 1

In the drawing, 1 denotes the main 110 drainage tube, 2 the auxiliary inflating tube, and 3 the distensible bag which is formed by an annular band the end portions of which are secured to the catheter body as aforesaid. The tubes 1 and 2 may 115 be formed by former immersion and then combined in well known way. The auxiliary tube 2 is provided with a branch portion 5 to which an inflating bulb may be connected.

In the production of the catheter, when the rubber constituting the catheter body is sufficiently dried, an aperture 6 is made in the auxiliary tube 2 by cutting or burning and the catheter body is inserted 125 through the annular band of rubber forming the bag.

body and relatively inextensible thread binding 7 (Fig. 4) is wound round such end portions in such a way that the innermost turn of thread at each end of the band 5 is positioned at the corresponding end boundary of the inflatable portion of the bag and maintains the sealing contact between the band and the catheter body around a circumferential line (9 in Figs. 4 and 5) lying in a plane perpendicular to the axis of the said body. The thread is held in position by an adhesive. After the bag has been secured, the assembly is again immersed in the liquid rubber composition 15 to deposit a thin film of rubber 8 over the assembly, which film merges with the previous rubber deposits to form an integral structure with a smooth exterior surface, and also serves to strengthen the union of 20 the bag with the catheter body.

Finally, the assembled catheter is subjected to the usual washing, drying, and if desired, vulcanising treatments, the deposition forms are removed from within the deposits, drainage eyelet 4 is cut or burned in an appropriate position, and the remote ends of the tubes 1, 2 and 5 are trimmed, all according to the usual procedure requiring no detailed explanation. 30 The finished catheter made by the process described, is seen to consist of a principal drainage tube 1 having a drainage eyelet 4 at the distal end, a distensible bag 3 of uniform length surrounding the body 35 of the catheter adjacent the eyelet 4 and secured to the catheter body by relatively inextensible bindings disposed at right angles to the axis of such body, and an auxiliary or distension duct 2 leading to the distensible bag whereby the bag may be distended by injecting air or a liquid through the duct. 40

If desired, the end portions of the bag forming band may be brought, prior to 45 binding, over annular grooves on the wall of the catheter body, in which case tensioning by stretching of the ends of the band in passing it over the body of the catheter, and the binding, may assist in bringing 50 the annular parts of the band into engagement with the grooves. The assembly may then, as before, be immersed in the liquid rubber composition to deposit a thin film of rubber over the assembly.

For causing the catheter, or a desired local portion of the catheter to show up more clearly in an X-ray photograph of a patient, the liquid rubber composition from which the catheter or a local portion 60 thereof is formed may be compounded with a suitable shadow-producing material. For example, the addition of 20% of blanc fixe (based on the rubber content) to latex, will produce a rubber article capable of 65 casting a clearly defined shadow under X-

rays. Other materials which block the travel of X-rays may be substituted for the blanc fixe.

In an alternative manner of producing the catheter, the catheter body is first 70 formed as hereinbefore described and then local circumferential areas of the catheter body corresponding to the desired location of the inflatable portion of the bag of uniform length as aforesaid are treated with 75 a substance adapted to prevent adhesion between such area of the body and a coating of rubber formed by deposition and a length of the catheter body having the said treated circumferential area as a 80 medial portion, is then immersed in a liquid rubber composition so as to form the bag. Examples of substances adapted to prevent adhesion as aforesaid are a suspension of soapstone in alcohol, 85 or a bromine, chlorine or sulphur chloride solution.

After such formation in situ the binding must be applied in the same way as when the band has been separately formed, so 90 as to maintain circumferential end boundaries to the inflatable portion of the band, such end boundaries being circles in parallel planes exactly or approximately at right angles to the axis of the catheter 95 body.

The catheter bag, in the form of a pre-formed annular band, may be formed by extrusion or by a dipping process.

As a particular example of the application 100 of the invention it may be used in the manufacture of a haemostatic bag (Foley's haemostatic bag), such as is designed for use after transurethral resection of the prostate, the distensible bag operating on 105 inflation to exert pressure in the prostatic cavity.

What we claim is:—

1. Bag catheter having its distensible bag connected by end portions surrounding 110 the catheter body, wherein at the end boundaries of the inflatable portion of the bag, sealing contact between the bag and the catheter body is maintained around circumferential lines lying in substantially 115 parallel planes exactly or approximately at right angles to the catheter body by relatively inextensible bindings.

2. Bag catheter as in Claim 1, wherein the bindings are maintained in position by 120 adhesion to the material of the bag.

3. Bag catheter as in Claim 1 or 2, wherein annular parts of the said end portions of the bag are drawn into annular grooves in the catheter body by the bind- 125 ings or these and the tension of such radially stretched end portions of the bag.

4. Bag catheter as in any preceding claim wherein the applied bindings are coated over with rubber. 130

5. Bag catheter consisting of a body portion as herein defined, drainage eyelet(s) at the distal end of the main drainage tube and a distensible bag surrounding the body of the catheter adjacent said eyelet(s), the auxiliary or distension duct leading to the interior of the distensible bag for distension of the latter by injection of air or a liquid through the duct, the bag catheter also having relatively inextensible bindings which maintain sealing contact between the bag and the catheter body at the opposed end boundaries of the inflatable portion of the bag around circumferential lines lying exactly or approximately in parallel planes substantially at right angles to the axis of the catheter body.

6. In the production of a bag catheter as in any preceding claim, treating a local circumferential area of the catheter body corresponding with the desired location of the inflatable portion of the bag with a substance adapted to prevent adhesion between such body and a subsequently applied rubber deposit, and then immersing a length of said body having the so treated area as its medial portion in a liquid rubber composition to produce the bag in situ and then applying the bindings around the end portions of the bag which are conjoined to the catheter body abreast of said treated area.

7. In the production of a bag catheter as in any preceding Claim 1 to 5, forming the catheter body as herein defined, by former immersion, forming an aperture(s) to lead from the auxiliary tube, to the bag

later to be secured to the catheter body, inserting the prepared catheter body through an annular bag forming band 40 until the band surrounds the aperture(s) and securing the end portions of the band to the catheter body by relatively inextensible bindings or these and an adhesive so that the bindings maintain sealing contact between the bag and the catheter body at the opposed end boundaries of the inflatable portion of the bag around circumferential lines lying in substantially parallel planes exactly or approximately 50 at right angles to the axis of the catheter body.

8. In the production of a bag catheter by the method according to Claim 6 or 7, the additional step of immersing the catheter bag and body assembly in a liquid rubber composition to deposit a thin film of rubber over such assembly which merges with the previous rubber deposits to form an integral structure with a finished exterior surface.

9. A bag catheter as in any preceding Claim 1 to 5 wholly or locally formed from a liquid rubber composition compounded with a suitable X-ray shadow-producing material.

10. Bag catheter substantially as herein described with reference to and as illustrated in the accompanying drawings.

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#### PROVISIONAL SPECIFICATIONS.

#### Rubber drainage Tubing, Catheters or the like with distensible bags and the manufacture thereof

WE, ROBERT HANS MULLER, F.R.S., a British Subject, and J. G. FRANKLIN & SONS LIMITED, a British Company, both of Birbeck Works, Colvestone Crescent, London, E.8, do hereby declare this invention to be described in the following statement:—

The present invention relates to rubber drainage tubing, catheters or the like with distensible bags (hereinafter termed bag catheters) and the manufacture thereof, and has for its principal object to provide a distensible bag catheter in which the bag will distend symmetrically or substantially so and the tubing remain straight or substantially so while the bag is distended. The term rubber as used in this specification is to be understood as including both natural and artificial rubber.

Distensible bag catheters generally consist of a principal drainage tube provided

with a circumferential bag portion proximal to the drainage eyelets, and having an independent distension duct extending longitudinally along the drainage tube to the bag for inflating this so as to distend the bag after the catheter is in place.

The manufacture of such catheters by a dipping process is well known.

It consists in depositing rubber from a solution or dispersion on a rod-like former to form the main drainage tube, attaching a thinner auxiliary tube alongside the main tube and affixing a thin rubber bag or bag-forming portion around the tubing in such a way that this bag portion adheres or connects firmly to the main tube at both its edges, but can be freely inflated through the auxiliary tube.

For preference this bag portion is not, however, before inflation a bag, but rather a thin annular band or sleeve or rubber

which initially, at least at its edges closely fits the outside of the drainage tube, being internally connected by adhesion at both edges to the body of the catheter. One or more external coatings of rubber may be applied to attach more securely the said band to said body. When such a band is distended to the bulbous or hollow ring-like configuration required in use, the rubber of the bag is necessarily greatly stretched and the forces exerted may tend partly to pull away the aforesaid edges from the body of the catheter so that the circumferential bands or zones of connection between such edges and the body of the catheter are rendered uneven so that not only is an unsymmetrically shaped bag formed on inflation, but the bag carrying end of the drainage tube is bent as a result thereof.

In the manufacture of these catheters therefore, one of the difficulties encountered is to produce an article in which the bag will distend symmetrically and in such a way that the main drainage tubing remains substantially straight and extends substantially centrally of the inflated bag in use.

We have found that the main factor requisite for a symmetrical distension of the bag, and also for preventing the drainage tube from bending, is the provision and maintenance under inflating pressure of a circumferential zone of connection between each end of the bag and the body of the catheter such that parallel planes containing the nearer boundaries of said zones shall be at right angles or substantially so to the axis of said body.

As considerable forces are exerted at the zones of attachment of the ends of the bag with the catheter body during the inflation of the bag, it is quite usual for the axial extent of one or both end connections to become so locally or unevenly reduced around the said zones or one of them at or adjacent the nearer boundaries or one of them, that the aforesaid condition, if originally present, viz., that parallel planes at right angles to the axis of the catheter body shall contain the nearer boundaries of the connecting zones, is not maintained.

These circumstances and also the usual method of production make it extremely difficult to ensure the maintenance of this condition of junction of the bag edges with the main body, and as soon as the forces exerted by the distended bag are not exerted around such a line of junction, a couple is produced and distortion of the bag and bending of the tube occurs.

For the purpose of firstly to ensure the

and secondly to preserve this condition, the present invention consists in reinforcing the junction zones aforesaid by a relatively inextensible binding such as of fabric or a suitable thread, for example, of rayon, cotton or silk wrapped firmly one or more times around the said edges and secured, the binding being disposed at right angles or substantially so as the axis of the catheter body.

In carrying the invention into practical effect the main and auxiliary tubing and the bag are produced, e.g., by immersion of suitable formers in liquid rubber composition and combined in the usual way. As hereinafter described the catheter body itself may be used as the former for production of the bag by immersion.

After the parts are combined at least one strip of fabric or one or more rounds of thread are firmly secured around the edges of the bag at right angles to the axis of the catheter body and further rubber is deposited, e.g., by dipping, on top of the combination.

The liquid rubber composition may be a solution of rubber in a solvent such as the so-called rubber cement, or a natural or artificial aqueous dispersion of rubber, and the rubber coatings may be produced upon the formers in any desired manner. The composition may contain vulcanising ingredients or may consist of pre-vulcanised dispersions.

Cohesion of the rubber ordinarily will be sufficient to hold the assembled forms in proper relation for subsequent handling, but may be augmented, if necessary, by rubber cement. The assembled coated forms are then immersed again in the liquid rubber composition and an additional coating of rubber is produced upon the assembly to build up a deposit of rubber merging with the previous deposits to provide an overall coating about 0.01 to 0.10 thick.

When the rubber deposits are sufficiently dried an aperture is produced by cutting or burning, leading from the auxiliary tubing to the bag presently to be applied to the catheter body. For this purpose the prepared catheter body is inserted through the bag (thin annular band or sleeve of rubber) until the bag surrounds the cut or burn aforesaid and the edge portions of the bag found as aforesaid, previously, if desired, to binding, being brought into alignment with and pressed into annular grooves on the wall of said body, tension by stretching of the edges in passing the body of the catheter through the band or sleeve, and the binding, assisting in this operation of engaging the

immersed in the liquid rubber composition to deposit a thin film of rubber over the assembly which merges with the previous rubber deposits to form an integral structure and also further serves to secure the bag to the body of the catheter, and promote a smooth exterior surface especially when the grooving aforesaid is not present.

Finally, the assembled catheter is subjected to the usual washing, drying, and, if desired, vulcanising treatments, the deposition forms are removed from within the deposits, drainage eyelets are cut or burned in appropriate positions, and the ends of the outlet tubes are trimmed, all according to the usual procedure requiring no detailed explanation.

The finished catheter made by the process described, is seen to consist of a principal drainage tube having drainage eyelets at the distal end, a distensible bag surrounding the main body of the catheter adjacent the eyelets and secured by relatively inextensible binding disposed at right angles to the axis of the catheter body with an auxiliary or distension duct leading into and through the integral body of the catheter to the distensible bag, whereby the bag may be distended by injecting air or a liquid through the duct.

For causing the catheter, or a desired local portion of the catheter, to show up more clearly in an X-ray photograph of a patient, the liquid rubber composition from which the catheter or the local portion thereof may be formed may be compounded with a suitable shadow-producing material. For example, the addition of 20% of blanc fixe (based on the rubber content) to latex,

will produce a rubber article capable of casting a clearly defined shadow under X-rays. Other materials which block the travel of X-rays may be substituted for the blanc fixe.

The local circumferential area of the catheter body where the bag is desired to be may be treated with a substance adapted to prevent adhesion in that area of the bag forming wall of the annular band aforesaid, or so treating such area the bag may be formed in situ by deposition. For example, a local circumferential area or surface band of the rubber body of the catheter including the opening, may be treated with a separating material such as a suspension of soapstone in alcohol, or with a chemical such as bromine, chlorine, or sulphur chloride, in a suitable solvent, to prevent adhesion of the subsequently applied rubber deposit, and then immersed in a liquid rubber composition to produce the final coating of rubber forming the distensible bag in situ over the treated area.

The annular band aforesaid may be performed by extrusion, or by a dipping process.

As a particular example of the application of the invention, it may be used in the manufacture of a haemostatic bag (Foley's haemostatic bag), such as is designed for use after transurethral resection of the prostate, the distensible bag being inflated to exert pressure in the prostatic cavity.

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Printed for Her Majesty's Stationery Office by Wickes & Andrews, Ltd., E.C.4. 39/244.—1953.  
Published at The Patent Office, 25, Southampton Buildings, London, W.C.2 from which copies may be obtained.

# SPECIFICATION NO. 693,224

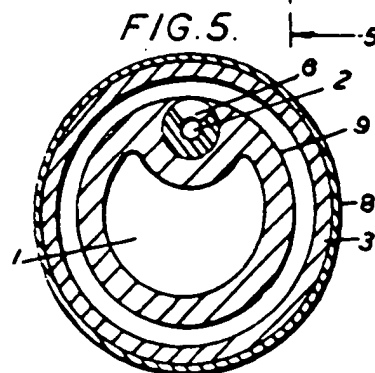
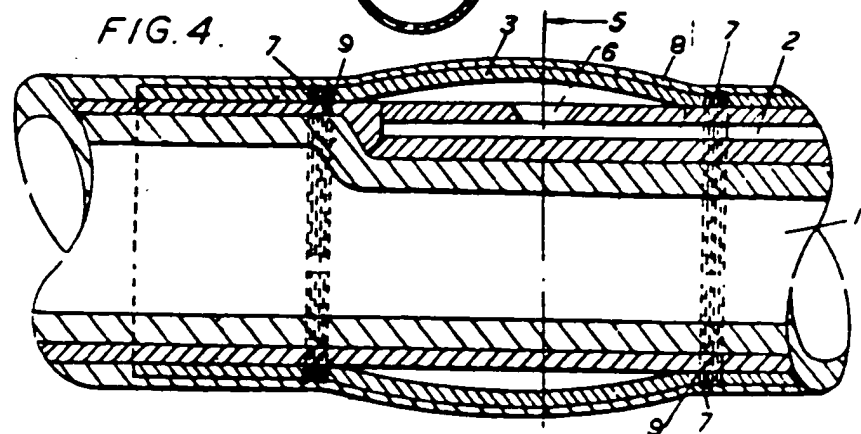
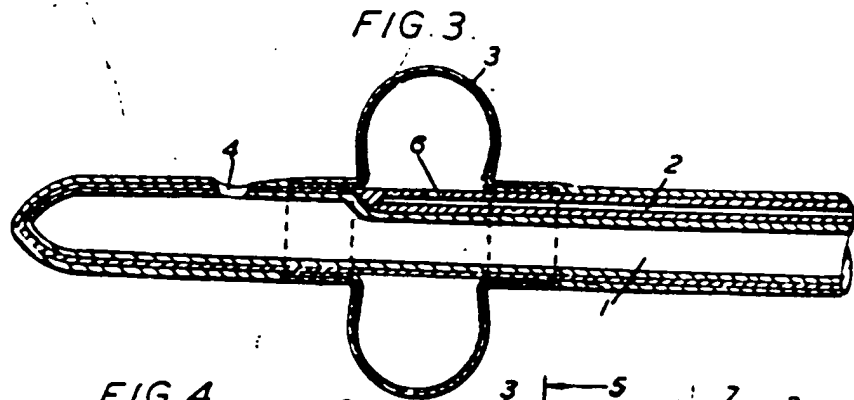
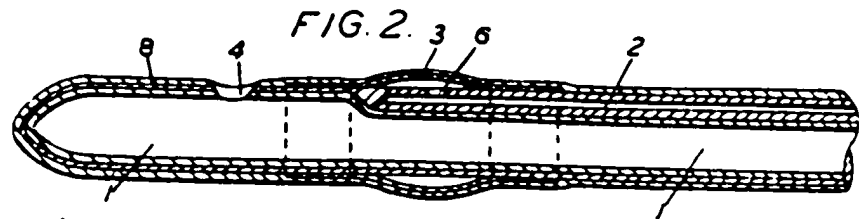
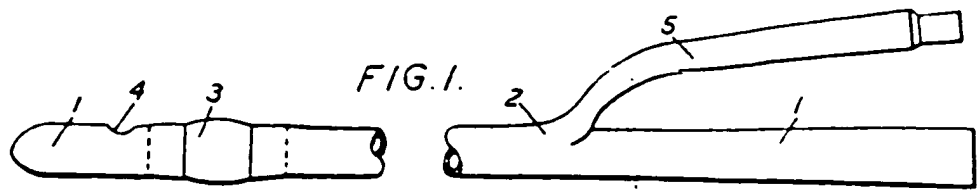
INVENTOR:— ROBERT HANS MULLER

By a direction given under Section 17(1) of the Patents Act 1949 this application proceeded in the name of J. G. Franklin & Sons Limited, a British company, of Birkbeck Works, Colvestone Crescent, London, E.8.

THE PATENT OFFICE,

2nd July, 1953

DB 31392/1(15)/3467 150 6/53 R



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